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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/090,173  | 03/06/2002  | Michael K. Gunaratnam | JPD-4398-211        | 7110             |
| 23117 7590 04/25/2008<br>NIXON & VANDERHYE, PC<br>901 NORTH GLEBE ROAD, 11TH FLOOR<br>ARLINGTON, VA 22203 |             |                       |                     |                  |
| EXAMINER  |             |                       |                     |                  |
| DIXON, ANNETTE FREDRICKA  |             |                       |                     |                  |
| ART UNIT  |             | PAPER NUMBER          |                     |                  |
| 3771  |             |                       |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/090,173

**Applicant(s)**

GUNARATNAM ET AL.

**Examiner**

Annette F. Dixon

**Art Unit**

3771

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-35, 39, 62, 63 and 71-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-35, 39, 62, 63 and 71-106 is/are rejected.
- 7) ☒ Claim(s) 71-106 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This Office Action is in response to the amendment filed on April 8, 2008. Examiner acknowledges claims 33-35, 39, 62, 63, 71-106 are pending in this application, with claims 33 and 39 having been currently amended, claims 1-32, 36-38, 40-61, and 64-70 having been cancelled, and claims 71-106 having been newly added.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 39, 62, 63, 78-81, 85, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph (6,192, 886).

As to Claims 39, 62, and 63, Rudolph discloses a respiratory mask (5) and headgear (the combination of elements 8 and 9) comprising: a respiratory mask (5) having a rigid mask frame (13), adjustable headgear (the combination of elements 8 and 9) for securing said mask on a patient, said headgear (the combination of elements 8 and 9) including at least one attachment strap (9), said mask frame (13) having rigidly secured thereto a rigid first connector portion (90), and a second connector portion (10) adapted for releasable mating with said first connector portion, wherein said first and second connector portions (the combination of elements 90 and 10, respectively) form a press-release between said mask frame and said strap. (Column 6, Lines 28-43).

Further, Rudolph discloses a plurality of connectors as seen in Figures 1-3). Yet Rudolph does not expressly disclose the first connector portion to be a female connector and the second connector portion to be a male connector. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the first connector to be female and attached to the mask and the second connector to be male and attached to the strap, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Further, one of ordinary skill in the art would not expect the rearrangement of parts to adversely affect the effectiveness of the mask to be secured to the patient for operation.

As to Claims 78, and 85, Rudolph discloses the female connector (93) is secured to the front wall portion of the mask frame (13) (via the male connector 90) when the device is donned. (Figures 1, 3, and 7).

As to Claims 79, and 86, Rudolph discloses the female connector (93) is secured to the mask frame (13) to permit the male connector (90) to be connected and disconnected from the female connector portion (93) in a single-hand operation. Regarding the limitation of a single-hand operation, the ability of the mask device to be removed in by a single hand is a function of the patient's hand and finger flexibility and dexterity.

As to Claim 80, Rudolph discloses the mask frame (13) includes a front wall portion defining a forward end of the mask, the front wall portion having a circular gas inlet aperture (20) configured to connect to a gas delivery conduit (the combination of elements 6, 7, and 78), the mask frame (13) including a pair of inclined side wall

portions and a base portion (best seen in Figure 3) having a portion thereof connecting to the front wall portion. (Figures 1-3).

As to Claim 81, Rudolph discloses the mask frame (13) includes a rim (17) at the rear for attaching a cushion (33).

4. Claims 33-35 and 71-76, 82, 83, 88-91, 92-103, 105, 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph (6,192, 886) in view of Ferrero et al. (5,657,493).

As to Claims 33, 87, and 99, Rudolph discloses all the recited elements, yet does not expressly disclose the use of a cantilever member with the connector elements. However, at the time the invention was made the use of cantilever members in mask connectors was well known. Specifically, Ferrero teaches the cantilever member (the combination of elements 30 and 36) has a leading end (the portion containing element 44), a trailing end (the portion containing element 56) and a release portion (56), and a locking portion (58). (Figures 5-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the cantilever member in combination with the male connector on the strap, as taught by Ferrero, for the purpose of retaining the strap and mask on the user.

As to Claim 34, Rudolph discloses a gas delivery conduit (78) attached to the front wall portion of the mask frame. (Figures 1 and 2).

As to Claim 35, Rudolph discloses a mask frame (13) has a rim (17) for enabling a cushion (33) to be applied. (Figures 1 and 2).

As to Claims 71, 74, 88, and 91, Ferrero teaches at least one groove on the trailing end (the portion containing element 56) for facilitating a positive grip by the user. (Column 4, Lines 1-3). Regarding claim 74, as the trailing end is apart of the cantilever member, the grooves of the trailing end meet the claim limitations.

As to Claims 72, 73, 82, 83, 89, 90, 105 and 106, Ferrero teaches the locking element (34) comprises two lugs (49) on opposite sides of the cantilever member (the operation of elements 30 and 36). As seen in Figure 7, each lug (49) acts as a wedge to be incorporated into the female connector.

As to Claims 75, 92, 93, 97, and 98, Ferrero teaches an arcuate ridge (63) between the ridge structure (60) and the locking element (34). (Figures 5-8).

As to Claims 76 and 94, Ferrero teaches a pair of spaced portions (52, Column 3, Lines 56-58) and a cross bar (44) define an aperture configured to receive the end of at least one strap portion (40). (Figures 5 and 8, Column 3, Lines 50-60)

As to Claims 95 and 96, the system of Rudolph and Ferrero teaches all the recited elements with the exception of the size. It would have been an obvious matter of design choice to modify the size of the recited elements, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to Claim 100, Rudolph discloses the female connector (93) is secured to the mask frame (13) to permit the male connector (90) to be connected and disconnected from the female connector portion (93) in a single-hand operation. Regarding the

limitation of a single-hand operation, the ability of the mask device to be removed in by a single hand is a function of the patient's hand and finger flexibility and dexterity.

As to Claim 101, Rudolph discloses the mask frame (13) includes a front wall portion defining a forward end of the mask, the front wall portion having a circular gas inlet aperture (20) configured to connect to a gas delivery conduit (the combination of elements 6, 7, and 78), the mask frame (13) including a pair of inclined side wall portions and a base portion (best seen in Figure 3) having a portion thereof connecting to the front wall portion. (Figures 1-3).

As to Claim 102, Rudolph discloses the female connector (93) is secured to the front wall portion of the mask frame (13) (via the male connector 90) when the device is donned. (Figures 1, 3, and 7).

As to Claim 103, Rudolph discloses the mask frame (13) includes a rim (17) at the rear for attaching a cushion (33).

5. Claims 77, 84, 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph (6,192, 886) in view of Ferrero et al. (5,657,493) as applied to claims 33, 39, and 99 above, and further in view of Sullivan (5,243,971).

As to Claims 77, 84, 104, the system of Rudolph and Ferrero discloses a respiratory mask; yet, does not expressly disclose the use of an extension configured for attachment the attachment of a forehead support. However, at the time the invention was made the use of an extension piece attached to the mask for the forehead support was known. Specifically, Sullivan teaches a extension (29) with a cushion (30) for

retaining the position of the mask in the desired location on the face . (Column 3, Lines 1-5 and Column 4, Lines 45-55). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system to include the extension for forehead support as taught by Sullivan to ensure proper placement of the mask on the face of the user.

### ***Response to Arguments***

6. Applicant's arguments filed April 8, 2008 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not teach or fairly suggest the recited orientation of the male and female connectors on the respiratory mask. However, Examiner respectfully disagrees with Applicant's assertion. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Further, Applicant has not provided the Examiner with any proof or reasoning as to how or why the arrangement of the male and female connectors from the mask region to the strap region would inhibit the operation and ability of the airflow mask to properly function. Finally, Examiner presents prior art Lane (5,555,569) as extrinsic evidence of the teaching of a male connector (120) positioned on the strapping region and a female connector (106) positioned on the mask region for the purpose of retaining the mask region to the strap region. (Figure 7, Column 4). Thus, in light of the aforementioned reasoning the rejection of claims 33-35, 39, 62, and 63 has been maintained.



Art Unit: 3771

7. Applicant's arguments, filed April 8, 2008, with respect to the rejection(s) of claim(s) 71-106 under 35 U.S.C. §112, first paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Rudolph (6,192, 886) in view of Ferrero et al. (5,657,493).

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lane (5,555,569).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771

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